Section 8 – 510(k) Summary

APR 0 5 2013

Date:	27 December 2012
Sponsor:	Apogee OrthoSolutions, LLC 2513 Greenview Drive, Uniontown, OH 44685 Phone: 330.899.0881
Contact Person:	Spanky Raymond, Manager
Trade Names:	Monster Screw System™
Device Classification	Class II
Classification Name:	Smooth or threaded metallic bone fixation fastener, Single/multiple component metallic bone fixation appliances and accessories
Regulation:	888.3040, 888.3030
Device Product Code:	HWC, HTN
Device Description:	The Monster Screw System™ is comprised of bone screws and washers. The Monster Screw is a threaded bone screw offered in 2.0mm to 9.5mm diameters (in 0.5 mm increments) having overall lengths from 8mm (for smaller diameters) thru 200mm (for larger diameters). The screws are offered having a variety of features with respect to head, thread, tip, cannulation and material. Size-matched washers are also available in flat, dome and bowl configurations.
Intended Use:	The Monster Screw System™ is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device.
Materials:	The Monster Screw System™ implants are manufactured from medical grade titanium alloy (per ASTM F136) and stainless steel alloy (per ASTM F2229).
Predicate Devices:	Vilex Inc (K973309, K991151, K991197 and K014154) OsteoMed Corp. (K924018) OrthoHelix (K060428) Zimmer, Inc. (K112885 [with Pioneer K102903]) Smith & Nephew (K060736, K090675 and K111994) Synthes, Inc. (K962011, K962823, K963172, K012945, K021932, K050636 and K090949)
Performance Data:	Mechanical testing of the worst case Monster Screws included torsion, insertion/removal and pullout performed according to ASTM F543. The mechanical test results and theoretical comparisons demonstrated that the Monster Screw System™ mechanical performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The Monster Screw System™ possesses the same technological characteristics as one or more of the predicate devices. These include:

- performance (as described above),
- basic design (threaded fastener),
- material (titanium and/or stainless steel alloys) and
- sizes (dimensions are comparable to those offered by the predicate systems).

Therefore the fundamental scientific technology of the Monster Screw System™ is the same as previously cleared devices.

Conclusion:

The Monster Screw System™ possesses the same intended use and technological characteristics as the predicate devices. Therefore the Monster Screw System™ is substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Apogee OrthoSolutions, LLC
% Mr. Spanky Raymond
Manager
2513 Greenview Drive
Uniontown, Ohio 44685

Letter dated: April 5, 2013

Re: K124027
Trade/Device Name: Monster Screw System™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: March 7, 2013
Received: March 8, 2013

Dear Mr. Raymond:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 – Indications for Use Statement

510(k) Number: K124027

Device Name: Monster Screw System™

Indications for Use:

The Monster Screw System™ is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices